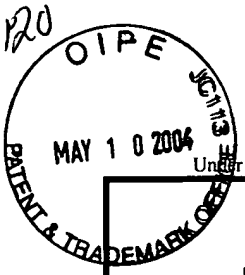
120



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TRANSMITTAL FORM

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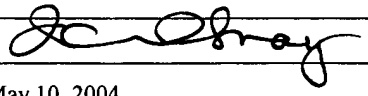
		Application Number	10/066,426
		Filing Date	January 30, 2002
		First Named Inventor	Mark Mathis
		Art Unit	3738
		Examiner Name	T. Barrett
Total Number of Pages in This Submission	30	Attorney Docket Number	29912-706.201

ENCLOSURES *(Check all that apply)*

☒ Fee Transmittal Form	☐ Drawing(s)	☐ After Allowance communication to Technology Center (TC)
☒ Fee Attached (deposit account)	☐ Licensing-related Papers	☒ Appellants' Brief Pursuant To 37 C.F.R. 1.192
☐ Amendment/Reply	☐ Petition	☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
☐ After Final	☐ Petition to Convert to a Provisional Application	☐ Proprietary Information
☐ Affidavits/declaration(s)	☐ Power of Attorney, Revocation Change of Correspondence Address	☐ Status Letter
☐ Extension of Time Request	☐ Terminal Disclaimer	☐ Other Enclosure(s) (please identify below):
☐ Express Abandonment Request	☐ Request for Refund	
☐ Information Disclosure Statement	☐ CD, Number of CD(s)	
☐ Certified Copy of Priority Document(s)	Remarks	
☐ Response to Missing Parts/ Incomplete Application		
☐ Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm or Individual name	James R. Shay, Reg. No. 32,062, WILSON SONSINI GOODRICH & ROSATI
Signature	
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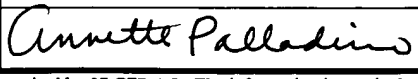
Signature		Date	May 10, 2004

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 165.00

Complete if Known	
Application Number	10/066,426
Filing Date	January 30, 2002
First Named Inventor	Mark Mathis
Examiner Name	T. Barrett
Art Unit	3738
Attorney Docket No.	29912-706.201

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 23-2415

Deposit Account Name: Wilson Sonsini Goodrich & Rosati

The Director is authorized to: (*check all that apply*)

☐ Charge fee(s) indicated below ☐ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment fee(s)

☐ Charge fees(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below		Fee Paid
Total Claims		-20** =		x		=	
Independent Claims		-3** =		x		=	
Multiple Dependent						=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	**Reissue independent claims over original patent
1205	18	2205	9	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)0

***or number previously paid, if greater; For Reissues, see below*

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	$165.00
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) $ 165.00

SUBMITTED BY

(Complete *(if applicable)*)

Name *(Print/Type)*	James R. Shay	Registration No. *(Attorney/Agent)*	32,062	*Telephone*	650-493-9300
Signature		Date	May 10, 2004		

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APPEAL BRIEF
Atty. Docket No. 29912-706.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of	
Mark MATHIS, et al.	
Appln. No.: 10/066,426	
Confirmation No.: 5095	Group Art Unit: 3738
Filed: January 30, 2002	Examiner: T. Barrett
"Fixed Length Anchor and Pull Mitral Valve Device and Method"	

APPELLANTS' BRIEF PURSUANT TO 37 C.F.R. § 1.192

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant submits the following brief in accordance with the provisions of 37 C.F.R. § 1.192 in response to the Final Rejection mailed October 14, 2003. This brief is being filed in triplicate. Unless a check is submitted herewith for the fee required under 37 C.F.R. § 1.192(a) and 1.17(c), please charge said fee to Deposit Account No. 23-2415. Appellant's Notice of Appeal was filed on March 12, 2004. Therefore, this appeal brief is timely filed.

I. REAL PARTY IN INTEREST

The real party in interest is CARDIAC DIMENSIONS, INC. (Assignee) by virtue of an assignment executed by the inventors (Appellant) and recorded by the Assignment Branch of the U.S. Patent and Trademark Office on January 30, 2002 (at Reel 012570, Frame 0732).

II. RELATED APPEALS AND INTERFERENCES

Appellant states that, upon information and belief, Appellant is not aware of any co-pending appeal or interference which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

The application under appeal currently includes claims 1-36, 42 and 43. Claims 37-41 have been cancelled.

Claims 1-2, 7, 8, 14, 19-32 and 42 stand rejected as anticipated under 35 U.S.C. § 102(e). by Langberg WO 01/54618 A1 (hereinafter "Langberg").

Claims 1-6, 8-13, 15, 17, 33-37, 39 and 43 stand rejected as anticipated under 35 U.S.C. § 102(e) by Solem US 6,210,432 (hereinafter "Solem"). Claims 37 and 39 have been cancelled.

Claims 1, 15-18, and 37-41 stand rejected as anticipated under 35 U.S.C. § 102(e) by Pai US 2003/0078465 A1 (hereinafter "Pai"). Claims 37-41 have been cancelled.

The rejections of claims 1-36, 42 and 43 are appealed.

IV. STATUS OF AMENDMENTS

An Amendment After Final Rejection was filed on December 12, 2003. The Examiner indicated in an Advisory Action, mailed January 21, 2004, that the proposed amendments presented in the Amendment After Final Rejection would be entered on filing of a Notice of Appeal and an Appeal Brief. The Notice of Appeal was filed March 12, 2004. The claims set forth in the APPENDIX as required by 37 C.F.R. §1.192 (c)(9) correspond to claims as amended

by the Amendment After Final Rejection filed December 12, 2003. Accordingly, all Amendments have been entered.

V. SUMMARY OF THE INVENTION

Embodiments of the present invention as claimed in the appealed claims will be described below with reference to page and line numbers in United States Patent Application number 10/066,426 entitled "Fixed Length Anchor and Pull Mitral Valve Device and Method" by Mathis et al. as filed January 30, 2002.

Independent claim 1 recites a device that effects mitral valve annulus geometry of a heart as illustrated in at least the embodiments of mitral valve therapy devices 30 and 70 of Figures 2-5 and Figure 6, respectively. As shown in those drawings, a first anchor is disposed within the coronary sinus 14 and adjacent to the mitral valve annulus 20. A second anchor is illustrated in a position proximal to the first anchor and also adjacent the mitral valve annulus 20. A connecting member having a fixed length is permanently attached to the first and second anchors. When the first and second anchors are within the heart with the first anchor anchored in the coronary sinus, the second anchor may be displaced proximally to effect the geometry of the mitral valve annulus and released to maintain the effect on the mitral valve geometry. Support for this claim is found, at least, on page 6, lines 12-28; page 11, line 18 - page 15, line 15; and Figures 2-7.

Claims 2-7, 15-18 and 42 depend from independent claim 1. Support for the limitations found in each of these claims can be found, at least, in the sections detailed below.

Claim 2 further defines an embodiment of the second anchor that, when deployed, is configured to anchor against distal movement and moveable in a proximal direction. Support for this claim is found, at least, on page 6, lines 12-28; page 11, line 18 - page 15, line 15; and Figures 2-7.

Claim 3 further defines an embodiment of the first anchor of claim 2 in that the first anchor is self-deploying upon release in the coronary sinus. Support for this claim is found, at

least, on page 6, line 30; page 11, line 25 – page 12, line 2; page 13, lines 27-29; page 15, lines 9-15; and Figures 2-7.

Claim 4 further defines an embodiment of the second anchor of claim 2 that is self-deploying upon release in the coronary sinus. Support for this claim is found, at least, on page 6, line 30; page 12, lines 13-15; page 13, line 30 – page 14, line 2; page 15, lines 9-15; and Figures 2-7.

Claim 5 further defines an embodiment of connecting member of claim 2 that is a rigid member. Support for this claim is found, at least, on page 6, line 31 – page 7, line 2; page 12, lines 6-9; and Figures 2-5 and 7.

Claim 6 further defines an embodiment of the connecting member of claim 2 that the includes a spring having a maximum length. Support for this claim is found, at least, on page 6, line 31 – page 7, line 4; page 7, line 4; page 15, lines 2-4; and Figure 6.

Claim 7 further defines an embodiment of the connecting member of claim 2 that is flexible and nonstretchable. Support for this claim is found, at least, on page 6, line 31 – page 7; line 4 and Figures 2-5 and 7.

Claim 42 further defines an embodiment of the connecting member of claim 1 that is flexible and nonstretchable. Support for this claim is found, at least, on page 6, line 31 – page 7; line 4 and Figures 2-5 and 7.

Claims 15–18 recite embodiments of the first and second anchors of the device of claim 1 where the anchors occupy less than all of the coronary sinus to permit a cardiac lead to be passed and where the anchor include a loop, as illustrated particularly in Figure 7. Support for these claims is found, at least, on page 9, lines 13–31; page 16, line 27 – page 17, line 13; and Figures 2-7.

Independent claim 8 recites an embodiment of the invention that is a device for effecting mitral valve annulus geometry of a heart, comprising first anchor means for anchoring in the coronary sinus of the heart adjacent the mitral valve annulus; second anchor means deployable within the heart proximal to the first anchor means and adjacent the mitral valve annulus for

anchoring against movement; connecting means having a fixed length and permanently connecting the first anchor means to the second anchor means; whereby when the first and second anchor means are within the heart with the first anchor means deployed, the second anchor means may be displaced proximally for cooperating with the first anchor means and the connecting means for effecting the geometry of the mitral valve annulus and released for maintaining the effect on the mitral valve geometry. Support for this claim is found, at least, on page 6, lines 12-28; page 11, line 18 - page 15, line 15; and Figures 2-7.

Dependent claims 9-14 depend from independent claim 8. Support for the limitations in each of these claims may be found, at least, in the detailed page and line citations that follow.

Claim 9 recites an embodiment of the second anchor means of claim 8 where, when deployed, anchors against distal movement and is moveable in a proximal direction. Support for this claim is found, at least, on page 6, lines 12-28; page 11, line 18 - page 15, line 15; and Figures 2-7.

Claim 10 recites an embodiment of the first anchor means of claim 8 that is self-deploying upon release in the coronary sinus. Support for this claim is found, at least, on page 6, line 30; page 11, line 25 – page 12, line 2; page 13, lines 27-29; page 15, lines 9-15; and Figures 2-7.

Claim 11 recites an embodiment of the second anchor means of claim 8 where the second anchor means is self-deploying upon release in the coronary sinus. Support for this claim is found, at least, on page 6, line 30; page 12, lines 13-15; page 13, line 30 – page 14, line 2; page 15, lines 9-15; and Figures 2-7.

Claim 12 recites an embodiment of the connecting means of claim 8 where the connecting means is a rigid member. Support for this claim is found, at least, on page 6, line 31 – page 7, line 2; page 12, lines 6-9; and Figures 2-5 and 7.

Claim 13 recites an embodiment of the connecting means of claim 8 where the connecting means includes a spring having a maximum length. Support for this claim is found, at least, on page 6, line 31 – page 7, line 4; page 7, line 4; page 15, lines 2-4; and Figure 6.

Claim 14 recites an embodiment of the connecting means of claim 8 where the connecting means is flexible and nonstretchable. Support for this claim is found, at least, on page 6, line 31 – page 7 line 4 and Figures 2-5 and 7.

Independent claim 19 recites an embodiment of the invention of a system that effects mitral valve annulus geometry of a heart, comprising:

a mitral valve device including a first anchor configured to be positioned within and anchored to the coronary sinus 14 of the heart 10 adjacent the mitral valve annulus 20 within the heart, a second anchor configured to be positioned within the heart proximal to the first anchor and adjacent the mitral valve annulus within the heart, and a connecting member having a fixed length permanently attached to the first and second anchors;

a catheter 52 having a distal end, a proximal end and a lumen that receives the device, the catheter being guidable into the coronary sinus adjacent to the mitral valve annulus and deploying the first and second anchors of the device within the coronary sinus adjacent to the mitral valve annulus; and

a tether 54 releasably coupled to the second anchor and extending proximally through the lumen and out of the catheter proximal end, whereby

when the first anchor is deployed by the catheter in the coronary sinus, the second anchor may be displaced proximally by proximally pulling on the tether to effect the geometry of the mitral valve annulus and thereafter released for deployment to maintain the effect on the mitral valve geometry.

Claim 19 is supported, at least, on page 7 line 20 – page 8, line 10; page 13, line 14 – page 14, line 30; and Figures 3-5.

Dependent claims 20-25 depend from independent claim 19. Support for the limitations in each of these claims may be found, at least, in the detailed page and line citations that follow.

Claim 20 recites an embodiment of the second anchor of the system of claim 19 where the second anchor 36, when deployed, is anchored against distal movement and moveable in a

proximal direction. Support for this claim is found, at least, on page 7 line 20 – page 8, line 10; page 13, line 14 – page 14, line 30; and Figures 3-5.

Claim 21 recites an embodiment of the first anchor of the system of claim 19 where the first anchor is self-deploying upon release in the coronary sinus. Support for this claim is found, at least, on page 11, line 25 – page 12, line 2; page 13, lines 27-29; page 15, lines 9-15; and Figures 2-7.

Claim 22 recites an embodiment of the second anchor 36 of the system of claim 19 where the second anchor is self-deploying upon release in the coronary sinus. Support for this claim is found, at least, on page 12, lines 13-15; page 13, line 30 – page 14, line 2; page 15, lines 9-15; and Figures 2-7.

Claim 23 recites an embodiment of the connecting member of the system of claim 19 where the connecting member is a rigid member. Support for this claim is found, at least, on page 6, line 31 – page 7, line 2; page 12, lines 6-9; and Figures 2-5 and 7.

Claim 24 recites an embodiment of the connecting member of the system of claim 19 where the connecting member includes a spring having a maximum length. Support for this claim is found, at least, on page 6, line 31 – page 7, line 4; page 7, line 4; page 15, lines 2-4; and Figure 6.

Claim 25 recites an embodiment of the connecting member of the system of claim 19 where the connecting member is flexible and nonstretchable. Support for this claim is found, at least, on page 6, line 31 – page 7; line 4 and Figures 2-5 and 7.

Independent claim 26 recites an embodiment of a method of the invention for effecting mitral valve annulus geometry in a heart, the method including the steps of:

fixing a first anchor within the coronary sinus of the heart adjacent to the mitral valve annulus;

positioning a second anchor within the heart proximal to the first anchor;

fixing a fixed length connecting member, between the first anchor and the second anchor;

displacing the second anchor proximally, to effect the geometry of the mitral valve annulus; and

releasing the second anchor from further proximal displacement to maintain the effect on the mitral valve geometry. Support for claim 26 may be found, at least, on page 8, lines 11-22; page 11, line 18 - page 15, line 15; and Figures 2-7.

Dependent claims 27 and 28 depend from independent claim 26. Support for the limitations of the dependent claims is supported, at least, in the sections discussed below.

Claim 27 is an embodiment of the displacing step of the method of claim 26 wherein the displacing step includes the steps of releasably coupling a tether to the second anchor and pulling proximally on the tether. Support for this claim is found, at least, on page 8, line 3 and page 13, line 14 – page 14, line 14.

Claim 28 recites an embodiment of the displacing step of the method of claim 27 including the further step of removing the tether from the second anchor after the releasing step. Support for this claim is found, at least, on page 14, lines 10-14.

Independent claim 29 recites an embodiment of the invention for a method of effecting mitral valve geometry of a heart, the method including the steps of:

advancing a guide catheter into the coronary sinus of the heart adjacent to the mitral valve annulus;

feeding a self-deploying first anchor down and out of the guide catheter to deploy the first anchor in the coronary sinus adjacent to the mitral valve annulus;

connecting a fixed length connecting member between the first anchor and a self-deploying second anchor that once deployed anchors at least against distal movement;

guiding the second self-deploying anchor down the guide catheter to a position within the coronary sinus proximal to the first anchor;

displacing the second anchor proximally to effect the geometry of the mitral valve annulus;

withdrawing the guide catheter to release and deploy the second anchor; and

releasing the second anchor to deploy the second anchor and maintain the effect on the mitral valve annulus geometry. Support for this claim may be found, at least, on page 8, lines 11-22; page 11, line 18 – page 13, line 13; page 13, line 14 – page 14, line 30; and Figures 3-5.

Claims 30, 31 and 32 depend from claim 31.

Claim 30 recites an embodiment of the method of claim 29 including the further step of releasably coupling a tether to the second anchor prior to the displacing step. Support for this claim is found, at least, on page 8, line 3 and page 14, lines 12-14.

Claim 31 recites an embodiment of the method of claim 30 wherein the displacing step includes the step of pulling proximally on the tether. Support for this claim is found, at least, on page 14, lines 5-8 and Figures 3-5.

Claim 32 recites an embodiment of the method of claim 29 wherein the feeding step includes locating the first anchor proximally to the circumflex artery within the coronary sinus. Support for this claim is found, at least, on page 11, line 30 – page 12, line 5 and Figure 2.

Independent claim 33 recites an embodiment of the invention that is a device that effects mitral valve annulus geometry of a heart, comprising:

a first anchor configured to be positioned within and anchored to the coronary sinus of the heart adjacent the mitral valve annulus within the heart;

a second anchor configured to be positioned within the heart proximal to the first anchor and adjacent the mitral valve annulus within the heart; and

a connecting member attached between the first and second anchors,

at least one of the first and second anchors deploying to anchor against movement in a first direction while being moveable in a second direction opposite the first direction. Support for this claim is found, at least, on page 8, line 22 – page 9, line 12; page 11, line 18 - page 15, line 15; and Figures 2-7.

Claim 34, depends from claim 33, and recites an embodiment of the device of claim 33 wherein the at least one anchor is the first anchor wherein the first direction is a proximal

direction and wherein the second direction is a distal direction. Support for this claim is found, at least, on page 8, line 22 – page 9, line 12; page 11, line 18 - page 15, line 15; and Figures 2-7.

Claim 35, depends from claim 33, and recites an embodiment of the device of claim 33 wherein at least one anchor is the second anchor wherein the first direction is a distal direction and wherein the second direction is a proximal direction. Support for this claim is found, at least, on page 8, line 22 – page 9, line 12; page 11, line 18 - page 15, line 15; and Figures 2-7.

Claim 36, depends from claim 33, and recites an embodiment of the device of claim 33 wherein the first anchor anchors against movement in a proximal direction and is moveable in a distal direction and wherein the second anchor anchors against movement in the distal direction and is moveable in the proximal direction. Support for this claim is found, at least, on page 8, line 22 – page 9, line 12; page 11, line 18 - page 15, line 15; and Figures 2-7.

Independent claim 43 recites an embodiment of the invention for a device for providing therapy to a mitral valve annulus of a heart, the device being elongated and dimensioned to be received within the coronary sinus of the heart adjacent to the mitral valve annulus, the device having a first radius of curvature when initially placed in the coronary sinus adjacent the mitral valve annulus and a second radius of curvature when providing therapy to the mitral valve annulus from within the coronary sinus, the second radius of curvature being greater than the first radius of curvature. Support for this claim is found, at least, in Figures 3-6.

VI. ISSUES

Appellants respectfully request the Board of Patent Appeals and Interferences to review the following issues on appeal:

1. Whether claim 1 is anticipated by Langberg 35 U.S.C. § 102(e)
2. Whether claim 1 is anticipated by Solem under 35 U.S.C. § 102(e)
3. Whether claim 1 is anticipated by Pai under 35 U.S.C. § 102(e)
4. Whether claim 8 is anticipated by Langberg under 35 U.S.C. § 102(e)
5. Whether claim 8 is anticipated by Solem under 35 U.S.C. § 102(e)

6. Whether claim 19 is anticipated by Langberg under 35 U.S.C. § 102(e)
7. Whether claim 26 is anticipated by Langberg under 35 U.S.C. § 102(e)
8. Whether claim 29 is anticipated by Langberg under 35 U.S.C. § 102(e)
9. Whether claim 33 is anticipated by Solem under 35 U.S.C. § 102(e)
10. Whether claim 43 is anticipated by Solem under 35 U.S.C. § 102(e)

VII. GROUPING OF CLAIMS

Appellants do not intend claims 1-36, 42 and 43 to stand or fall together. Rather, Appellants will prove the patentability of claimed embodiments of the invention over the prior art of record according to each independent claim grouped with its dependent claims. Accordingly, Group 1 includes independent claim 1 and dependent claims 2-7, 15-18 and 42. Group 2 includes independent claim 8 and dependent claims 9-14. Group 3 includes independent claim 19 and dependent claims 20-25. Group 4 includes independent claim 26 and dependent claims 27 and 28. Group 5 includes independent claim 29 and dependent claims 30-32. Group 6 includes independent claim 33 and dependent claims 34-36. Group 7 includes the independent claim 43.

Each of the above named groups of claims will stand or fall separately from one another. The reasons these seven groups of claims should stand or fall separately are set forth in the Argument section below.

VIII. ARGUMENTS

Appellants respectfully submit that all of claims 1-36, 42 and 43 are in proper form and are separately patentable over the prior art of record. More specifically, Appellants contend that none of the claims on appeal are anticipated by any of Langberg, Solem or Pai.

Citations below are made to page, column, line or paragraph numbers found in World Intellectual Property Organization publication number WO 01/54618 A1 published 02 August 2001 in the case of Langberg, issued U.S. Patent 6,210,432 in the case of Solem, and United

States Patent Application Publication number US 2003/0078465 A1 published April 24, 2003 in the case of Pai.

The legal standard for anticipation

The Examiner's rejections in this case are based on express and inherent anticipation. "A prior art reference anticipates a claim only if the reference discloses, either expressly or inherently, every limitation of the claim. . . . Absence from the reference of any claimed element negates anticipation." Rowe v. Dror, 112 F3.3d 473, 478, 42 USPQ2d 1550 (Fed. Cir. 1997); Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Anticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include—not just possibly include—any unstated limitation. Transclean Corp. v. Bridgewood Services, Inc., 290 F.3d 1364, 1373, 62 USPQ2d 1865 (Fed. Cir. 2002); Mentor H/S, Inc. v. Medical Device Alliance, Inc., 244 F. 3d 1365, 1376, 58 USPQ2d 1321 (Fed. Cir. 2001; In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed.Cir. 1999). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. . . . The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Robertson, 169 F.3d at 745.

Claims 1-36, 42 and 43 are patentable over the prior art of record under § 102

1. Langberg does not anticipate claim 1 under 35 U.S.C. § 102(e)

The Examiner rejected claim 1 under 35 U.S.C. § 102(e) as being anticipated by Langberg.

Claim 1 recites a device that effects mitral valve annulus geometry of a heart, comprising:

a first anchor configured to be positioned within and anchored to the coronary sinus of the heart adjacent to the mitral valve annulus within the heart;

a second anchor configured to be positioned within the heart proximal to the first anchor and adjacent the mitral valve annulus within the heart; and

a connecting member having a fixed length permanently attached to the first and second anchors, whereby

when the first and second anchors are within the heart with the first anchor anchored in the coronary sinus, the second anchor may be displaced proximally to effect the geometry of the mitral valve annulus and released to maintain the effect on the mitral valve.

In order for a reference to anticipate claim 1, every claim element must be present in the reference. If a single claim element from the claim is not present in the reference, then the reference fails to anticipate the claim. As demonstrated below, Langberg fails to anticipate claim 1 because it does not disclose each element recited in claim 1.

Device 40 in Langberg's first embodiment has a transitional region 50 which, by deflecting out of the plane of the coronary sinus 22, serves as an anchor 52 and prevents the device 40 from slipping out of the coronary sinus 22 when tension is applied. (Langberg, page 15, lines 16-19.) The proximal end 42 of the device lies outside the ostium of the coronary sinus and is curved upward so as to anchor against the posterior aspect of the interatrial septum. (Langberg, page 15, lines 12-23). Tension is applied to device 40 by proximal and distal movement of a "forming element" 56. (Langberg, page 17, lines 5-31.) A locking ring 70 on the forming element 56 maintains the shape of the device by preventing the forming element from slipping distally once the device 40 has been curved.

The Examiner's rejection of claim 1 points to Langberg's alleged disclosure of a first distal anchor and a second proximal anchor. The Examiner fails to address the specific requirements of claim 1 that the anchors be structured so that "when the first and second anchors are within the heart with the first anchor anchored in the coronary sinus, the second anchor may be displaced proximally to effect the geometry of the mitral valve annulus and released to maintain the effect on the mitral valve geometry." In fact, Langberg's device lacks structure configured in that way, and Langberg does not even suggest that such structure would be

desirable or even possible. Langberg's first embodiment therefore fails to anticipate claim 1 under 35 U.S.C. 102(e).

Langberg's second embodiment (see Langberg page 23, lines 12-19; not illustrated in any figure) replaces the forming element with a core of a pre-formed springy memory material. The memory material core is pre-formed to have the desired configuration that, when released into the coronary venous system, applies the requisite force to remodel the annulus. This embodiment fails to correct the deficiencies of Langberg's first embodiment described above in anticipating claim 1 and therefore does not anticipate claim 1 under § 102(e).

Langberg's third embodiment is a ventricular girdle 100, the body 102 is formed into a loop using first and second control wires 108, 110 to alter the mitral valve geometry. Once the mitral valve geometry has been adjusted, the position of the first and second control wires 108, 110 are held in place by the locking clip 112. (Langberg page 23 line 19 – page 24 line 30, Figs. 5 and 6). This embodiment is even further from the invention recited in claim 1 and fails to anticipate claim 1 under § 102(e).

For at least these reasons, the rejection of claim 1 (and claims 2, 7, and 42 which depend from and are grouped with claim 1) under 35 U.S.C. § 102(e) as being anticipated by Langberg is improper and should be overturned.

2. Solem does not anticipate claim 1 under 35 U.S.C. § 102(e)

The Examiner rejected claim 1 under 35 U.S.C. § 102(e) as being anticipated by Solem. Solem describes three embodiments of a device for treatment of mitral annulus dilation comprising an elongate body having two states. One embodiment, elongated body 8, is described with reference to Solem col. 3 line 26 – col.4 line 45 and Figs. 1-9. An alternative embodiment, elongated body 8', is described with reference to Solem col. 4 lines 46-55 and Figs. 10 and 11. A third embodiment, elongated body 8", is described with reference to Solem col. 4 line 56 – col. 5 line 4. None of these embodiments anticipates claim 1.

The Examiner's rejection focuses on Figures 2 and 3 of Solem.[1] Specifically, the Examiner points to hooks 10 in Solem Fig. 3 as the anchors recited in claim 1. Solem describes hooks 10 as being structured to "dig into the walls of the coronary sinus 5 and into the heart." Solem does not disclose or suggest that after one of the hooks has been dug into the coronary sinus wall and into the heart, another hook may be displaced proximally to effect the geometry of the mitral valve annulus and released to maintain the effect on the mitral valve. Rather, Solem discloses the delivery and deployment of all hooks simultaneously, with none of the hooks being moved in any direction after being dug into the heart. For at least these reasons, Solem does not anticipate claim 1, and the rejection of claim 1 (and claims 2-6, 15 and 17 which depend from and are grouped with claim 1) under 35 U.S.C. § 102(e) as being anticipated by Solem is improper and should be overturned.

3. Pai does not anticipate claim 1 under 35 U.S.C. § 102(e)

The Examiner rejected claim 1 under 35 U.S.C. § 102(e) as being anticipated by Pai. The Examiner set forth the argument underlying his rejection in two sentences in the Final Rejection: (1) "Pai et al. discloses a device comprising a first distal anchor loop and a second proximal anchor loop (Fig. 8A) connected to each other by a fixed length connecting member (4)." (2) "Pai et al. inherently discloses an anchor that is deploy***able***, which can permit another anchor to be displaced." (Emphasis in original.) The Examiner's determination of inherency, however, is contrary to established case law, as discussed above.

Pai describes a number of tensioning structures for remodeling ventricular structure. These tensioning structures are secured by either anchors 32 or loop anchors 96. Pai discloses more than 28 alternatives of an "anchor 32." Pai also discloses at least two alternatives of a

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[1] In the Office Action mailed May 6, 2003, the Examiner's rejection of claim 1 in view of Solem refers to Solem Fig. 10. On page 2 of the Final Rejection, however, the Examiner attempted to clarify his rejection by stating that the he intended to refer to element 10 in Figs. 2 and 3. The Examiner repeated the reference to Fig. 10 on page 3 of the Final Rejection, however. Appellants will assume the Examiner's rejection is based on Solem Figs. 2 and 3.

"loop anchor 96." Every embodiment, however, has anchors that simply anchor. Any tension added to the device after deployment is accomplished by means of a tensioning structure, such as described in Pai paragraph 141 and Fig. 29.

None of the Pai embodiments meets the requirement of claim 1 that the anchors be structured so that "when the first and second anchors are within the heart with the first anchor anchored in the coronary sinus, the second anchor may be displaced proximally to effect the geometry of the mitral valve annulus and released to maintain the effect on the mitral valve geometry." Pai does not even suggest that such structure would be desirable or even possible, nor has the Examiner pointed to any evidence, extrinsic or otherwise, that any of Pai's devices are necessarily structured to function in that way, as required by the case law discussed above. For at least these reasons, Pai does not anticipate claim 1, and the rejection of claim 1 (and claims 15-18 which depend from and are grouped with claim 1) under 35 U.S.C. § 102(e) as being anticipated by Pai is improper and should be overturned.

4. Langberg does not anticipate claim 8 under 35 U.S.C. § 102(e)

The Examiner rejected claim 8 under 35 U.S.C. § 102(e) as being anticipated by Langberg.

Claim 8 recites a device for effecting mitral valve annulus geometry of a heart, comprising:

first anchor means for anchoring in the coronary sinus of the heart;

second anchor means deployable within the heart proximal to the first anchor means and adjacent the mitral valve annulus for anchoring against movement; and

connecting means having a fixed length and permanently connecting the first anchor means to the second anchor means, whereby

when the first and second anchor means are within the heart with the first anchor means deployed, the second anchor means may be displaced proximally for cooperating with the first

anchor means and the connecting means for effecting the geometry of the mitral valve annulus and released for maintaining the effect on the mitral valve geometry.

Claim 8 is recited in means plus function format. The Examiner's rejection does not specifically set forth any analysis showing how any of Langberg's embodiments (1) performs the function set forth in the final clause ("whereby when the first and second anchor means are within the heart with the first anchor means deployed, the second anchor means may be displaced proximally for cooperating with the first anchor means and the connecting means for effecting the geometry of the mitral valve annulus and released for maintaining the effect on the mitral valve geometry") or (2) performs any of the functions set forth in claim 8 with structure that is equivalent to the structure disclosed in Appellants' specification and drawings. The Examiner has therefore failed to state a prima facie basis for this rejection.

Moreover, there is no disclosure (inherent or otherwise) in Langberg of a device capable of performing the function recited in claim 8. In addition, Langberg's structure, such as Langberg's forming element and means for anchoring, is not equivalent to Appellants' structure. For at least these reasons, the rejection of claim 8 (and claim 14 depending from and grouped with claim 8) under 35 U.S.C. § 102(e) as being anticipated by Langberg is therefore improper and should be overturned.

5. Solem does not anticipate claim 8 under 35 U.S.C. § 102(e)

The Examiner rejected claim 8 under 35 U.S.C. § 102(e) as being anticipated by Solem. As stated above, claim 8 is recited in means plus function format. The Examiner's rejection does not specifically set forth any analysis showing how any of Solem's embodiments (1) performs the function set forth in the final clause of the claim or (2) performs any of the functions set forth in claim 8 with structure that is equivalent to the structure disclosed in Appellants' specification and drawings. The Examiner has therefore failed to state a prima facie basis for this rejection.

Moreover, there is no disclosure (inherent or otherwise) in Solem of a device capable of performing the function recited in claim 8. In addition, Solem's structure, such as Solem's

hooks, is not equivalent to Appellants' structure. For at least these reasons, the rejection of claim 8 (and claims 9-13 depending from and grouped with claim 8) under 35 U.S.C. § 102(e) as being anticipated by Solem is therefore improper and should be overturned.

6. Langberg does not anticipate claim 19 under 35 U.S.C. § 102(e)

The Examiner rejected claim 19 under 35 U.S.C. § 102(e) as being anticipated by Langberg.

Claim 19 recites a system that effects mitral valve annulus geometry of a heart, comprising:

a mitral valve device including a first anchor configured to be positioned within and anchored to the coronary sinus of the heart adjacent to the mitral valve annulus within the heart, a second anchor configured to be positioned within the heart proximal to the first anchor and adjacent the mitral valve annulus within the heart, and a connecting member having a fixed length permanently attached to the first and second anchors;

a catheter having a distal end, a proximal end, and a lumen that receives the device, the catheter being guidable into the coronary sinus adjacent to the mitral valve annulus and deploying the first and second anchors of the device within the coronary sinus adjacent to the mitral valve annulus; and

a tether releasably coupled to the second anchor and extending proximally through the lumen and out of the catheter proximal end, whereby

when the first anchor is deployed by the catheter in the coronary sinus, the second anchor may be displaced proximally by proximally pulling on the tether to effect the geometry of the mitral valve annulus and thereafter released for deployment to maintain the effect on the mitral valve annulus.

As discussed above with respect to claim 1, the Examiner's rejection of claim 19 points to Langberg's alleged disclosure of a first distal anchor and a second proximal anchor. The Examiner fails to address the specific requirements of claim 19, however, that the anchors be

structured so that when the first and second anchors are within the heart with the first anchor anchored in the coronary sinus, the second anchor may be displaced proximally to effect the geometry of the mitral valve annulus and released to maintain the effect on the mitral valve geometry. In fact, Langberg's device lacks structure configured in that way, and Langberg does not even suggest that such structure would be desirable or even possible. Langberg therefore fails to anticipate claim 1 under 35 U.S.C. 102(e).

In addition, claim 19 recites a tether that proximally displaces and releases the second anchor. The Examiner points to Langberg's element 64, the proximal extension of the forming element 56, to satisfy this claim requirement. Langberg's proximal element 64 does not move the proximal end 42 (i.e., the portion of Langberg's device suggested by the Examiner to be a proximal anchor). Rather, Langberg's proximal element 64 moves the forming element 56. Langberg does not disclose any movement of the proximal end 42 of the device. In fact, Langberg uses a surface 90 of his deployment system to prevent proximal movement of device 40 when proximal extension 64 is retracted. Langberg therefore fails to disclose this limitation of claim 19, and the rejection of claim 19 (and claims 20-25 depending from and grouped with claim 19) under 35 U.S.C. § 102(e) as being anticipated by Langberg is improper and should be overturned for at least this reason.

7. Langberg does not anticipate claim 26 under 35 U.S.C. § 102(e)

The Examiner rejected claim 26 under 35 U.S.C.§ 102(e) as being anticipated by Langberg.

Claim 26 recites a method of effecting mitral valve geometry of a heart, the method including the steps of:

fixing a first anchor within the coronary sinus of the heart adjacent to the mitral valve annulus;

positioning a second anchor within the heart proximal to the first anchor;

fixing a fixed length connecting member between the first anchor and the second anchor;

displacing the second anchor proximally to effect the geometry of the mitral valve annulus; and

releasing the second anchor from further proximal displacement to maintain the effect on the mitral valve geometry.

The Examiner's rejection does not specifically address how Langberg's description of the operation of his device discloses each element of method claim 26. The Examiner has therefore not made a prima facie case for the rejection of this claim.

As described above, Langberg's first two embodiments are operated by moving a forming element to change the shape of the device. Langberg does not disclose a method including the steps of displacing an anchor proximally and releasing that anchor to maintain an effect on mitral valve geometry. For at least these reasons, the rejection of claim 26 (and claims 27-28 depending from and grouped with claim 26) under 35 U.S.C. § 102(e) as being anticipated by Langberg is therefore improper and should be overturned.

8. Langberg does not anticipate claim 29 under 35 U.S.C. § 102(e)

The Examiner rejected claim 29 under 35 U.S.C. § 102(e) as being anticipated by Langberg. Claim 29 recites a method of effecting mitral valve geometry of a heart, the method including the steps of:

advancing a guide catheter into the coronary sinus of the heart adjacent to the mitral valve annulus;

feeding a self deploying first anchor down and out of the guide catheter to deploy the first anchor in the coronary sinus adjacent to the mitral valve annulus;

connecting a fixed length connecting member between the first anchor and a self deploying second anchor that once deployed anchors at least against distal movement;

guiding the second self-deploying anchor down the guide catheter to a position within the coronary sinus proximal to the first anchor;

displacing the second anchor proximally to effect the geometry of the mitral valve annulus;

withdrawing the guide catheter to release and deploy the second anchor; and

releasing the second anchor to deploy the second anchor and maintain the effect on the mitral valve annulus.

Once again, the Examiner's rejection does not specifically address how Langberg's description of the operation of his device discloses each element of method claim 29. The Examiner has therefore not made a prima facie case for the rejection of this claim.

Langberg's discussion of the interaction between his deployment system 72 and the device 40 begins on page 21. Langberg fails to disclose the steps of displacing an anchor proximally to effect the mitral valve annulus geometry, withdrawing a guide catheter to release and deploy the second anchor, and releasing the second anchor to maintain the effect on the mitral valve annulus. For at least these reasons, the rejection of claim 29 (and claims 30-32 depending from and grouped with claim 29) under 35 U.S.C. § 102(e) as being anticipated by Langberg is therefore improper and should be overturned.

9. Solem does not anticipate claim 33 under 35 U.S.C. § 102(e)

The Examiner rejected claim 33 under 35 U.S.C. § 102(e) as being anticipated by Solem. Claim 33 recites a device that effects mitral valve annulus geometry of a heart, comprising:

a first anchor configured to be positioned within and anchored to the coronary sinus of the heart adjacent to the mitral valve annulus within the heart;

a second anchor configured to be positioned within the heart proximal to the first anchor and adjacent the mitral valve annulus within the heart; and

a connecting member attached between the first and second anchors,

at least one of the first and second anchors deploying to anchor against movement in a first direction while being moveable in a second direction opposite the first direction.

The Examiner points to Solem's hooks 10 as deploying to anchor against movement in a first direction while being moveable in a second direction opposite the first direction. As stated above with respect to the rejection of claim 1 over Solem, Solem describes hooks 10 as being structured to "dig into the walls of the coronary sinus 5 and into the heart." Solem does not disclose or suggest that the hooks, once deployed and lodged in the patient's heart, could be moved again in any direction. Solem therefore fails to disclose this element of claim 33. For at least these reasons, the rejection of claim 33 (and claims 34-36 depending from and grouped with claim 33) under 35 U.S.C. § 102(e) as being anticipated by Solem is improper and should be overturned.

10. Solem does not anticipate claim 43 under 35 U.S.C. § 102(e)

The Examiner rejected claim 43 under 35 U.S.C. § 102(e) as being anticipated by Solem. Claim 43 recites a device for providing therapy to a mitral valve annulus of a heart, the device being elongated and dimensioned to be received within the coronary sinus of the heart adjacent to the mitral valve annulus, the device having a first radius of curvature when initially placed in the coronary sinus adjacent the mitral valve annulus and a second radius of curvature when providing therapy to the mitral valve annulus from within the coronary sinus, the second radius of curvature being greater than the first radius of curvature.

The Examiner asserts that the "Solem et al. device would have a second increased radius of curvature if the second anchor were displaced proximally . . . ." Solem does not suggest, however, that the proximal end of his device can or should be displaced proximally. In fact, the operation of hooks 10, by digging into the patient's heart, may very well preclude operation of the Solem device in that way. Solem therefore fails to meet this structural limitation of claim 43.

In addition, all of Solem's embodiments work in exactly the opposite way: The devices are delivered in a substantially straight configuration (i.e., with an infinitely large radius of curvature) and assume a bent configuration (i.e., a smaller radius of curvature) upon deployment.

For at least these reasons, the rejection of claim 43 under 35 U.S.C. § 102(e) as being anticipated by Solem is improper and should be overturned.

CONCLUSION

For the reasons stated above, claims 1-36, 42 and 43 are patentable over the prior art of record, and the rejections those claims 35 U.S.C. § 102(e) is improper and should be withdrawn. Appellants respectfully ask the Board to overturn the Examiner's rejection with instructions to allow the claims.

The USPTO is directed and authorized to charge all required fees to Deposit Account No. 23-2415.

Respectfully submitted,

Date: May 10, 2004

James R. Shay, Reg. No. 32062

APPENDIX

Claims on Appeal

1. A device that effects mitral valve annulus geometry of a heart, comprising:

a first anchor configured to be positioned within and anchored to the coronary sinus of the heart adjacent the mitral valve annulus within the heart;

a second anchor, configured to be positioned within the heart proximal to the first anchor and adjacent the mitral valve annulus within the heart; and

a connecting member having a fixed length permanently attached to the first and second anchors, whereby

when the first and second anchors are within the heart with the first anchor anchored in the coronary sinus, the second anchor may be displaced proximally to effect the geometry of the mitral valve annulus and released to maintain the effect on the mitral valve geometry.

2. The device of claim 1 wherein the second anchor, when deployed, is configured to anchor against distal movement and moveable in a proximal direction.

3. The device of claim 2 wherein the first anchor is self-deploying upon release in the coronary sinus.

4. The device of claim 2 wherein the second anchor is self-deploying upon release in the coronary sinus.

5. The device of claim 2 wherein the connecting member is a rigid member.

6. The device of claim 2 wherein the connecting member includes a spring having a maximum length.

7. The device of claim 2 wherein the connecting member is flexible and nonstretchable.

8. A device for effecting mitral valve annulus geometry of a heart, comprising:

first anchor means for anchoring in the coronary sinus of the heart adjacent the mitral valve annulus;

second anchor means deployable within the heart proximal to the first anchor means and adjacent the mitral valve annulus for anchoring against movement; and

connecting means having a fixed length and permanently connecting the first anchor means to the second anchor means, whereby

when the first and second anchor means are within the heart with the first anchor means deployed, the second anchor means may be displaced proximally for cooperating with the first anchor means and the connecting means for effecting the geometry of the mitral valve annulus and released for maintaining the effect on the mitral valve geometry.

9. The device of claim 8 wherein the second anchor means, when deployed, anchors against distal movement and is moveable in a proximal direction.

10. The device of claim 8 wherein the first anchor means is self-deploying upon release in the coronary sinus.

11. The device of claim 8 wherein the second anchor means is self-deploying upon release in the coronary sinus.

12. The device of claim 8 wherein the connecting means is a rigid member.

13. The device of claim 8 wherein the connecting means includes a spring having a maximum length.

14. The device of claim 8 wherein the connecting means is flexible and nonstretchable.

15. The device of claim 1 wherein the first anchor occupies less than all of the coronary sinus to permit a cardiac lead to be passed by the first anchor.

16. The device of claim 15 wherein the first anchor includes a loop through which the cardiac lead may be passed.

17. The device of claim 15 wherein the second anchor also occupies less than all of the coronary sinus to permit the cardiac lead to be passed by the second anchor.

18. The device of claim 17 wherein the second anchor includes a loop through which the cardiac lead may be passed.

19. A system that effects mitral valve annulus geometry of a heart, comprising:

a mitral valve device including a first anchor configured to be positioned within and anchored to the coronary sinus of the heart adjacent the mitral valve annulus within the heart, a second anchor configured to be positioned within the heart proximal to the first anchor and adjacent the mitral valve annulus within the heart, and a connecting member having a fixed length permanently attached to the first and second anchors;

a catheter having a distal end, a proximal end and a lumen that receives the device, the catheter being guidable into the coronary sinus adjacent to the mitral valve

annulus and deploying the first and second anchors of the device within the coronary sinus adjacent to the mitral valve annulus; and

a tether releasably coupled to the second anchor and extending proximally through the lumen and out of the catheter proximal end, whereby

when the first anchor is deployed by the catheter in the coronary sinus, the second anchor may be displaced proximally by proximally pulling on the tether to effect the geometry of the mitral valve annulus and thereafter released for deployment to maintain the effect on the mitral valve geometry.

20. The system of claim 19 wherein the second anchor, when deployed, is anchored against distal movement and moveable in a proximal direction.

21. The system of claim 19 wherein the first anchor is self-deploying upon release in the coronary sinus.

22. The system of claim 19 wherein the second anchor is self-deploying upon release in the coronary sinus.

23. The system of claim 19 wherein the connecting member is a rigid member.

24. The system of claim 19 wherein the connecting member includes a spring having a maximum length.

25. The system of claim 19 wherein the connecting member is flexible and nonstretchable.

26. A method of effecting mitral valve annulus geometry in a heart, the method including the steps of:

fixing a first anchor within the coronary sinus of the heart adjacent to the mitral valve annulus;

positioning a second anchor within the heart proximal to the first anchor;

fixing a fixed length connecting member, between the first anchor and the second anchor;

displacing the second anchor proximally, to effect the geometry of the mitral valve annulus; and

releasing the second anchor from further proximal displacement to maintain the effect on the mitral valve geometry.

27. The method of claim 26 wherein the displacing step includes the steps of releasably coupling a tether to the second anchor and pulling proximally on the tether.

28. The method of claim 27 including the further step of removing the tether from the second anchor after the releasing step.

29. A method of effecting mitral valve geometry of a heart, the method including the steps of:

advancing a guide catheter into the coronary sinus of the heart adjacent to the mitral valve annulus;

feeding a self-deploying first anchor down and out of the guide catheter to deploy the first anchor in the coronary sinus adjacent to the mitral valve annulus;

connecting a fixed length connecting member between the first anchor and a self-deploying second anchor that once deployed anchors at least against distal movement;

guiding the second self-deploying anchor down the guide catheter to a position within the coronary sinus proximal to the first anchor;

displacing the second anchor proximally to effect the geometry of the mitral valve annulus;

withdrawing the guide catheter to release and deploy the second anchor; and

releasing the second anchor to deploy the second anchor and maintain the effect on the mitral valve annulus geometry.

30. The method of claim 29 including the further step of releasably coupling a tether to the second anchor prior to the displacing step.

31. The method of claim 30 wherein the displacing step includes the step of pulling proximally on the tether.

32. The method of claim 29 wherein the feeding step includes locating the first anchor proximally to the circumflex artery within the coronary sinus.

33. A device that effects mitral valve annulus geometry of a heart, comprising:

a first anchor configured to be positioned within and anchored to the coronary sinus of the heart adjacent the mitral valve annulus within the heart;

a second anchor configured to be positioned within the heart proximal to the first anchor and adjacent the mitral valve annulus within the heart; and

a connecting member attached between the first and second anchors,

at least one of the first and second anchors deploying to anchor against movement in a first direction while being moveable in a second direction opposite the first direction.

34. The device of claim 33 wherein the at least one anchor is the first anchor wherein the first direction is a proximal direction and wherein the second direction is a distal direction.

35. The device of claim 33 wherein the at least one anchor is the second anchor wherein the first direction is a distal direction and wherein the second direction is a proximal direction.

36. The device of claim 33 wherein the first anchor anchors against movement in a proximal direction and is moveable in a distal direction and wherein the second anchor anchors against movement in the distal direction and is moveable in the proximal direction.

42. The device of claim 1 wherein the connecting member is flexible and nonstretchable.

43. A device for providing therapy to a mitral valve annulus of a heart, the device being elongated and dimensioned to be received within the coronary sinus of the heart adjacent to the mitral valve annulus, the device having a first radius of curvature when initially placed in the coronary sinus adjacent the mitral valve annulus and a second radius of curvature when providing therapy to the mitral valve annulus from within the coronary sinus, the second radius of curvature being greater than the first radius of curvature.